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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/921,143 | 08/03/2001 | Timothy Coleman | PF112P6 | 6449 |

22195 7590 08/11/2004

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| EXAMINER |
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QIAN, CELINE X

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| ART UNIT | PAPER NUMBER |
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1636

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

2004

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|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 09/921,143 | Applicant(s) COLEMAN, TIMOTHY | |
| | Examiner Celine X Qian | Art Unit 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 19 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,10,12 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,10,12 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 3, 5, 10, 12 and 14 are pending in the application.

This Office Action is in response to the Amendment filed on 5/19/04.

Response to Amendment

The rejection of claims 2 and 11 under 35 U.S.C. 101 is moot in light of Applicant's cancellation of the claims.

The rejection of claims 2, 3, 11 and 12 under 35 U.S.C. 112 1st paragraph has been withdrawn in light of Applicant's amendment of the claims.

The rejection of claims 1-5, 12 and 13 under 35 U.S.C. 112 2nd paragraph has been withdrawn in light of Applicant's amendment of the claims.

The double patenting warning to claims 10, 12 and 14 is maintained for reasons set forth of the record mailed on 3/9/04 and further discussed below.

The rejection of claims 1, 5, 10 and 14 under 35 U.S.C. 102 (a) is maintained for reasons set forth of the record mailed on 3/9/04 and further discussed below.

Claims 3 and 12 are rejected under 35 U.S.C. 103 (a) for reasons discussed below.

Response to Arguments

Claim Objections

Applicant is advised that should claims 1, 3 and 5 be found allowable, claims 10, 12 and 14 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the

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same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The scope of claims 1, 3 and 5 is same as the scope of claims 10, 12 and 14. The vector depicted in Figure 31 is the same vector that deposit with ATCC PTA-2185. Therefore, Applicants are reminded that should claims 1, 3 and 5 be found allowable, claims 10, 12 and 14 will be objected under 37 CFR 1.75 as being a substantial duplicate thereof.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 5, 10 and 14 are rejected under 35 U.S.C. 102(a) as being anticipated by Vale et al (Circulation, 1999, Vol.100, No. 18, p.I.22).

In response to this rejection, Applicants argue that the Vale reference does not disclose every element of the claimed invention, and fails to enable one skilled in the art to make the claimed construct. Applicants thus conclude that the claimed invention is not anticipated by the Vale reference.

This argument has been fully considered but deemed unpersuasive. The claims are drawn to an isolated nucleic acid molecule comprising the pVGI.1 expression vector and a host cell comprising said nucleic acid molecule. Vale et al. disclose a pVGI.1 vector that expresses VEGF2 (see abstract). Vale et al. further teach that the vector is directly injected into ischemic

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myocardium of porcine (see abstract), and thus the porcine myocardial cells would comprise said vector. Although the sequence of the plasmid expression vector pVGI.1 is not disclosed, absent evidence from the contrary, it is considered the same vector because it has the same nomenclature and encodes the same protein, VEGF2. Therefore, the Vale reference anticipates the instantly claimed invention and this rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vale et al., in view of Manniatis et al (Molecular Cloning, A Laboratory Manual, 1982, Cold Spring Harbor Laboratory).

The claims are drawn to a method of producing a host cell *in vitro* comprising transducing, transforming or transfecting the host cell with the nucleic acid molecule comprising the pVGI.1 expression vector.

Vale et al. teach a pVGI.1 vector that expresses VEGF2. However, Vale et al. do not teach a method of producing a host cell *in vitro* comprising transforming the host with the pVGI.1 vector *in vitro*.

Manniatis et al. teach a method of introducing plasmid DNA into E.coli.

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It would have been obvious to one of ordinary skill of art to introducing the pVGI.1 expression vector to an E.coli. host for the purpose of propagate the plasmid vector. One of ordinary skill in the art would have been motivated to do so to get large quantity of the vector for use in the gene transfer method taught by Vale et al. The level of skill in the art is high. Absent evidence from the contrary, one of ordinary skilled in the art would have reasonable expectation of success to produce an E.coli. host cell transformed with the vector *in vitro* since such method is taught by Manniatis et al. Therefore, the claimed invention would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

No claims are allowed.

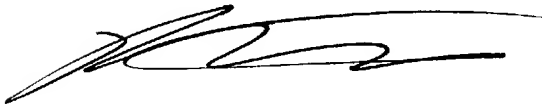
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.

A handwritten signature in black ink, appearing to be 'Celine Qian', written in a cursive style.